



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

December 30, 2015

Georgia Anastasiou
Agent for Lewis & Harrison
122 C Street, NW Suite 505
Washington, DC 20001

Subject: Notification per PRN 98-10 – Revised to Update Required Label Language
Product Name: ICX
EPA Registration Number: 79662-1
Application Date: December 15, 2015
Decision Number: 512407

Dear Ms. Anastasiou:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Antimicrobials Division (AD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped “Notification” and will be placed in our records.

Should you wish to add/retain a reference to the company’s website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product’s label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA’s Office of Enforcement and Compliance.

If you have any questions, you may contact Terria Northern at 703-347-0265 or via email at northern.terria@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Julie Chao", written over a horizontal line.

for

Julie Chao, Product Manager 33
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

12/30/15



A-dec® ICX® tablets are specially formulated to maintain dental unit waterlines and prevent accumulation of odor and foul taste bacteria.

Maintains dental unit water line effluent ≤10 CFU/ml

ACTIVE INGREDIENTS:

Sodium Percarbonate.....	6.96%
n-Alkyl(60% C ₁₄ 30% C ₁₆ 5% C ₁₂ 5% C ₁₈) dimethyl benzyl ammonium chloride	0.85%
n-Alkyl(68% C ₁₂ 32% C ₁₄) dimethyl ethylbenzyl ammonium chloride	0.85%
Silver Nitrate	0.14%
Other Ingredients.....	91.2%
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Total.....	100%

[Note to reviewer: EPA approved the location of the active ingredients statement on the back panel of the label on 12/15/09 in order to accommodate the small container size]

Net weight of tablet: 212.4 mg / 0.008 oz (2L application), 80.5 mg / 0.003 oz (0.7L application)
Net weight of product: 10.62 g / 0.375 oz (2L application), 4.03 g / 0.142 oz (0.7L application) – 50 tablets per box

**KEEP OUT OF REACH OF CHILDREN
WARNING**

[See insert for precautionary [language], first aid statements, and storage and disposal.]

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

Causes moderate eye irritation, wear protective eyewear. Avoid contact with eyes, skin or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

DIRECTIONS FOR USE:

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

ICX® is intended for use in general dental applications by providing water to the dental syringe, various handpiece ancillary devices, and cuspidor cupfill. When used according to these instructions for every bottle refill, optimum efficacy for control of odor and foul taste bacteria can be achieved.

Before Refilling Bottle

1. Empty any remaining water left in the bottle.
2. Drop tablet into an empty dental unit water bottle (0.7L tablet in 0.7 liter bottle, 2 L tablet in 2 liter). Avoid touching the tablet with unprotected skin.
3. Fill bottle with water and connect to the dental unit.
4. Wait 120 seconds for the tablet to fully dissolve.

NOTE -This product is intended for use with potable water and in conjunction with regular dental unit water testing, following flush (shock) treatment with an antimicrobial product registered with the U.S.EPA and recommended by the manufacturer

FIRST AID:

If solid product gets in eyes, hold eye open and rinse slowly and gently with water 15 to 20 minutes. Remove contact lenses, if present, after the first five minutes, then continue rinsing.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage disposal. Store at room temperature out of direct sunlight; DO NOT store above 30°C (86°F). Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available or dispose of empty outer foil pouch in the trash.

A-dec Inc., 2601 Crestview Drive, Newberg, Oregon 97132, USA

Phone: 1-800-547-1883 Fax: 503-537-2843

EPA Registration Number 79662-1

EPA Establishment Number:

Expiration Date: 28 months from manufacturing date

Made in USA